

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 26 FEB 2003

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| Applicant's or agent's file reference 500305/REO | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416). | |
| International Application No. PCT/AU02/00500 | International Filing Date (day/month/year) 18 April 2002 | Priority Date (day/month/year) 18 April 2001 |
| International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 5/00, A61F 11/04, A61N 1/36, H04R 25/00 | | |
| Applicant COCHLEAR LIMITED et al | | |

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| 1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36. |
| 2. This REPORT consists of a total of 4 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s). |
| 3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application |

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| Date of submission of the demand 13 June 2002 | Date of completion of the report 12 February 2003 |
| Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929 | Authorized Officer Geoff Sadlier Telephone No. (02) 6283 2114 |

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(h)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

| | | |
|-------------------------------|-------------|-----|
| Novelty (N) | Claims 1-79 | YES |
| | Claims | NO |
| Inventive step (IS) | Claims 1-79 | YES |
| | Claims | NO |
| Industrial applicability (IA) | Claims 1-79 | YES |
| | Claims | NO |

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 - HARTMAN et al.

D2 - US 4543956

D3 - US 4895152

D4 - US 4373531

D5 - US 4114627

D6 - WO 97/09863.

Novelty (N)

The claimed invention relates to a method and apparatus for measuring the response of nerves to electrical stimulation and is intended to address the problem of stimulus artefact.

The solution according to independent claims 1, 41 and 72 comprises a compensating stimulus which is applied after a first stimulus in order to counteract the artefact.

Claims 1 and 41 are further limited to the measurement of a neural response. The closest art of document D1 is also directed to this field and concerns the evaluation of electrically evoked brainstem potentials. Specifically D1 proposes a continuous sinusoidal stimulus that has an alternating polarity in order to minimise artefacts. However, D1 fails to disclose the application of a compensating stimulus specifically tailored to cancel a first stimulus and consequently the subject matter of claims 1 and 41 is new and meets the requirements of Article 33 PCT with regard to novelty and inventive step.

Claims 2-33 and 42-65 embody further aspects of this inventive concept and therefore also meet the requirements of Article 33.

Claim 72 is more broadly concerned with the measurement of any physiological response, each of the documents D2-D4 relate to cardiac pacemaker devices and to detection of an evoked response from the heart. Specifically D2 discloses a stimulating pulse that is followed by compensating pulse intended to electrically neutralise charges on the electrodes. D3 discloses a stimulating pulse that is followed by a charge dump pulse, which effectively reduces the electrode polarisation potential. D3 discloses a stimulation system that is intended to minimise the polarisation that occurs at a stimulus site. However, none of these documents suggests a compensatory stimulus subsequent to a first stimulus in order to counteract the stimulus artefact caused by the first stimulus. Consequently the subject matter of claim 72 is new and meets the requirements of Article 33 PCT with regard to novelty and inventive step.

Continued in supplemental box.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V.

Claims 73-79 embody further aspects of this inventive concept and therefore also meet the requirements of Article 33.

The solution according to independent claims 34 and 66 comprises short circuiting the stimulating electrode to a reference voltage immediately after applying the stimulus.

Document D5 discloses a cardiac pacemaker device which produces a stimulating pulse, at column 4, line 42 - column 5, line 13 of D5 a technique is disclosed which involves short circuiting to a reference voltage. However, the claimed invention differs from the cited art by being applied to the measurement of a neural response as opposed to the operation of a cardiac pacemaker this difference, furthermore D5 fails to address the issue of artefact compensation.

Therefore the subject matter of claims 34 and 66 is new and meets the requirements of Article 33 PCT with regard to novelty and inventive step.

Claims 35-40 and 67-71 embody further aspects of this inventive concept and therefore also meet the requirements of Article 33.